

EQUIMAX- ivermectin and praziquantel paste
Bimeda Inc

Equimax[®]
(ivermectin 1.87% / praziquantel 14.03%)
Paste
Anthelmintic and Boticide

FOR ORAL USE IN HORSES ONLY

Removes worms and bots with a single dose.

Contents will treat up to 1320 lb body weight.

Net Weight: 0.225 oz (6.42 g)

INDICATIONS

Consult your veterinarian for assistance in the diagnosis, treatment and control of parasitism. Equimax (ivermectin/praziquantel) Paste is indicated for the treatment and control of the following parasites:

Tapeworms

Anoplocephala perfoliata

Large Strongyles (adults)

Strongylus vulgaris (also early forms in blood vessels)

S. edentatus (also tissue stages)

S. equinus

Triodontophorus spp.

Small Strongyles (adults, including those resistant to some benzimidazole class compounds)

Cyathostomum spp.

Cylicocyclus spp.

Cylicostephanus spp.

Cylicodontophorus spp.

Small Strongyles (fourth-stage larvae)

Pinworms (adults and fourth-stage larvae)

Oxyuris equi

Ascarids (adults and third- and fourth-stage larvae)

Parascaris equorum

Hairworms (adults)

Trichostrongylus axei

Large-mouth Stomach Worms (adults)

Habronema muscae

Bots (oral and gastric stages)

Gasterophilus spp.

Lungworms (adults and fourth-stage larvae)

Dictyocaulus arnfieldi

Intestinal Threadworms (adults)

Strongyloides westeri

Summer Sores caused by *Habronema* and *Draschia* spp. cutaneous third-stage larvae

Dermatitis caused by **Neck Threadworm** microfilariae, *Onchocerca* sp.

DOSAGE AND ADMINISTRATION

This syringe contains sufficient paste to treat one 1320-lb horse at the recommended dose rate of 91 mcg ivermectin per lb (200 mcg/kg) and 0.68 mg praziquantel per lb (1.5 mg/kg) of body weight. Each weight marking on the syringe plunger delivers enough paste to treat 220 lb (100 kg) of body weight.

1. While holding plunger, turn the knurled ring on the plunger 1/4 turn to the left and slide it so the side nearest the barrel is at the prescribed weight marking.
2. Lock the ring in place by making a 1/4 turn to the right.
3. Make sure that the horse's mouth contains no feed.
4. Remove the cover from the tip of the syringe.
5. Insert the syringe tip into the horse's mouth at the space between the teeth.
6. Depress the plunger as far as it will go, depositing paste on the back of the tongue.
7. Immediately raise the horse's head for a few seconds after dosing.

Parasite Control Program

All horses should be included in a regular parasite control program with particular attention being paid to mares, foals, and yearlings. Foals should be treated initially at 4 weeks of age, and routine treatment repeated as appropriate. Consult your veterinarian for a control program to meet your specific needs. Equimax Paste effectively controls gastrointestinal nematodes, cestodes and bots of horses. Regular treatment will reduce the chances of colic caused by *Anoplocephala perfoliata* and verminous arteritis caused by *Strongylus vulgaris*.

Product Advantages

Broad-spectrum Control

Equimax Paste kills important internal parasites, including tapeworms, bots and the arterial stages of *S. vulgaris*, with a single dose. Equimax Paste contains two potent antiparasitic agents that are neither benzimidazoles nor organophosphates.

SAFETY

EQUIMAX Paste may be used in horses 4 weeks of age and older. Stallions and breeding, pregnant or lactating mares may be treated without adverse effects on fertility.

In a tolerance study in which 3- to 4-week-old foals were treated at 10X once, loose watery stools were observed on post-treatment days 1, 2, and 5-9 in one foal. These signs resolved without treatment by day 10, and no other foals were affected.

In a reproductive safety study, eleven mares were treated with a 3X dose of EQUIMAX Paste every two weeks throughout breeding, pregnancy and lactation, up until the foal was three months of age. Ten mares served as controls and were treated with the vehicle paste in a similar manner. An increased incidence of colic was observed in treated mares as compared to control mares. In addition, elevations of GGT and AST were more frequent in the 3X treated mares, and in two mares these enzymes were elevated at the time of colic episodes.

One treated mare was dropped from the study because she did not conceive after three breeding attempts.

Two treated mares had abnormally short diestrous periods of two days and eight days on the first estrous cycle following the birth of the study foal. In addition, one of these two mares failed to ovulate in the second and third estrous cycles.

In the first few weeks of life, foals born to the 3X treated mares had a higher incidence of transient ocular discharge and gastrointestinal disturbances (loose stools, diarrhea) and depression requiring medical intervention as compared to foals born to control mares.

PRECAUTIONS

Equimax Paste has been formulated specifically for use in horses and ponies **only**. This product should not be used in other animal species as severe adverse reactions, including fatalities in dogs, may result.

WARNING

Do not use in horses intended for human consumption.

HUMAN WARNINGS

Not for use in humans. Keep this and all drugs out of the reach of children. Refrain from eating or smoking when handling. Wash hands after use. Avoid contact with eyes. The Material Safety Data Sheet (MSDS) contains more detailed occupational safety information. To report adverse reactions in users, to obtain more information, or to obtain a MSDS, contact Bimeda Inc. at 1-888-524-6332.

ENVIRONMENTAL WARNINGS

Ivermectin and excreted ivermectin residues may adversely affect aquatic organisms. Do not contaminate ground or surface water. Dispose of the syringe in an approved landfill or by incineration.

Store at room temperature (25°C/77°F), with excursions permitted between 15°–30°C (59°–86°F).

NOTE TO USER

Swelling and itching reactions after treatment with ivermectin paste have occurred in horses carrying heavy infections of neck threadworm (*Onchocerca* sp. *microfilariae*). These reactions were most likely the result of microfilariae dying in large numbers. Symptomatic treatment may be advisable. Consult your veterinarian should any such reactions occur. Healing of summer sores involving extensive tissue changes may require other appropriate therapy in conjunction with treatment with Equimax Paste. Reinfection, and measures for its prevention, should also be considered. Consult your veterinarian if the condition does not improve.

To report adverse reactions, call Bimeda Inc. at 1-888-524-6332.

NADA #141-215, Approved by FDA

Manufactured by:

Virbac AH Inc.
3200 Meacham Blvd
Fort Worth, Texas 76137
U.S. Patent No. 5,824,653

Distributed by:

Bimeda, Inc.
Le Sueur, MN 56058

Made in USA

Equimax is a Registered Trademark of Virbac SA.

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October 2009

PRINCIPAL DISPLAY PANEL - 6.42 g Syringe Carton

EQUIMAX®

(ivermectin 1.87%/
praziquantel 14.03%)

Paste

Anthelmintic and Boticide

For the treatment and control of roundworms (ascarids, strongyles and lungworms), tapeworms, and bots in horses with a single dose.

Contents will treat up to 1320 lb body weight.

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EQUIMAX

ivermectin and praziquantel paste

Product Information

Product Type	OTC ANIMAL DRUG	Item Code (Source)	NDC:6 1133-7000
Route of Administration	ORAL	DEA Schedule	

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ivermectin (UNII: 8883YP2R6D) (ivermectin - UNII:8883YP2R6D)	ivermectin	200 ug
praziquantel (UNII: 6490C9U457) (praziquantel - UNII:6490C9U457)	praziquantel	1.5 mg

Product Characteristics

Color	WHITE	Score	
Shape		Size	
Flavor	APPLE	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:6 1133-7000-1	1 in 1 CARTON		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NADA	NADA141215	01/14/2010	

Labeler - Bimeda Inc (043653216)

Registrant - Virbac AH Inc (131568396)

Establishment

Name	Address	ID/FEI	Business Operations
Virbac Bridgeton		808558100	MANUFACTURE

Revised: 1/2010

Bimeda Inc